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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,579	01/25/2001	Hector F. DeLuca	960296.95700	4517

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,579

Applicant(s)

DELUCA ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/14/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

AS

DETAILED ACTION

1. Amendment filed on February 14, 2005 has been entered. claims 1-5, 11-15 are pending.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-5, 11-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mathieu et al US Patent 5,665,387.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

3. Applicant argues that Mathieus' patent is not enabling for the purposes of "reducing the risk of Type I diabetes in a predisposed human patient by up to 90%." (see Arguments at page 7, 2nd para.). Applicant Offers a Declaration of Inventor Julia Zella to demonstrate that Mathieus' disclosure was inoperative in treating diabetes. (Id.)

Here applicant appears to argue that the intended use of the method claims is not enabled in Mathieu. However, in a claim drawn to a process, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Mathieu teaches the exact same process steps. Thus, the instantly recited clinical outcome is inherent to the methods described in Mathieu.

Under the principles of inherency, if the prior art necessarily functions in accordance with or includes the claimed limitations, it anticipates it. There is no

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patentably distinct manipulative step between the methods of Mathieu and those of the instant claims. Accordingly, Examiner maintains the rejection.

4. Applicant appears to argue that the submitted Declaration shows that Mathieu is not enabling or operative for anticipation purposes. (see Arguments at page 8). In response, Examiner states that prior art reference must be considered together with the knowledge of one of ordinary skill in the pertinent art. In re Samour, 571, F.2d 559, 562, 197 USPQ 1, 3-4 (CCPQ 1978). A reference need not, however, explain every detail since it is speaking to those of skilled in the art. Here, the level of skill in the art is advanced and directed to clinical practitioners who understand the steps described in Mathieu. One of ordinary skill in the art viewing Mathieu's method steps would have been able to exercise such steps to treat diabetes.

For example, Mathieu teaches methods of treating autoimmune diabetes type I, which is caused by autoimmune destruction of B cells comprising administering tablets of 1a, 25-dihydroxyvitamin D (1,25 (OH)₂D₃) to a subject within at similar doses as instantly claimed. (see abstract, col 2, lines 1-10, col 10, lines 1-41, claim 4, 12-17). Autoimmune destruction of B cells leads to Type I diabetes. Mathieu also teaches that his compositions can be orally for treating diabetes. (see col 4, line 45-55). Therefore, one of ordinary skill in the art practicing Mathieu would have practiced the same method steps as those instantly claimed. Accordingly, the clinical end point would have ultimately and inherently been achieved.

Moreover, Applicant's Declaration relies on different vehicle systems. Mathieu's disclosure and patented claims are not limited to only arachis oil. rather an oral

composition containing vitamin D. Further, Examiner has noted that aside from the explicit recitation of the claimed intended purpose, the instant application discloses and claims no more than what is disclosed in the Mathieu's method steps. Accordingly, since the disclosure of the instant application fails to explicitly provide any additional detailed information concerning the claimed invention, Examiner has assumed that anyone desiring to carry out such method claims would have known what the final clinical outcome would have been.

Considering the above reasoning, Examiner maintains the rejection.

Conclusion

5. **No claims are allowed. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

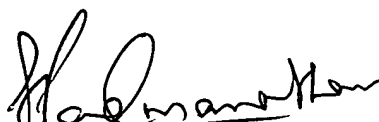
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER